



WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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8/22/2023 8:35:46 AM

Office of West Virginia  
Secretary Of State

## NOTICE OF RULE MODIFICATION OF A PROPOSED RULE

AGENCY: Health

RULE TYPE: Legislative

TITLE-SERIES: 64-91

RULE NAME: NEWBORN SCREENING SYSTEM

CITE AUTHORITY: 16-22-3

The above proposed Legislative rules, following review by the Legislative Rule Making Review Committee, is hereby modified as a result of review and comment by the Legislative Rule Making Review Committee. The attached modifications are filed with the Secretary of State.

**BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.**

Yes

**April L Robertson -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.**

64CSR91

TITLE 64  
LEGISLATIVE RULE  
DEPARTMENT OF HEALTH AND HUMAN RESOURCES  
BUREAU FOR PUBLIC HEALTH

SERIES 91  
NEWBORN SCREENING SYSTEM

**§64-91-1. General.**

1.1. Scope. -- This rule directs the Bureau for Public Health, in cooperation with other state agencies and attending physicians, to provide medical, dietary, and related assistance to children determined to be afflicted with any disease specified in W. Va. Code §16-22-3, and certain other diseases specified by the Bureau for Public Health. The rule provides for a means of payment for the required screenings, and any further referral or treatment services considered necessary by the Bureau for Public Health to implement the provisions of the statute on newborn screening. This rule should be read in conjunction with W. Va. Code §16-22-3 and §16-22A-1 *et seq.* and the rule on Newborn Hearing Screening, 64CSR24. The W. Va. Code is available in public libraries and on the Legislature's website, <http://wvlegislature.gov/>

1.2. Authority. -- W. Va. Code §16-1-4, §16-22-3 and §16-22A-3.

1.3. Filing Date. -- ~~April 4, 2019.~~

1.4. Effective Date. -- ~~April 4, 2019.~~

1.5. Sunset Provision. -- This rule shall terminate and have no further force or effect on ~~April 4, 2024~~ August 1, 2029.

1.6. The fee for a newborn screening system kit established in section 6 of this rule supersedes the amount in the Bureau for Public Health's "Fees for Services" rule, 64CSR51, Appendix A.

**§64-91-2. Application and Enforcement.**

2.1. Application. -- This rule applies to all infants born in West Virginia and to the hospital or birthing facility in which an infant is born, the parents or legal guardians, the physician attending a newborn child, or any person attending a newborn child not under the care of a physician and the director of the state laboratory performing mandatory newborn screening tests.

2.2. Enforcement. -- This rule is enforced by the Commissioner of the Bureau for Public Health.

**§64-91-3. Definitions.**

3.1. Birthing Facility. -- Any licensed medical facility that offers birthing services.

3.2. Bureau. -- The Bureau for Public Health in the West Virginia Department of Health and Human Resources. The bureau is the agency responsible for administering the Newborn Screening System.

3.3. Commissioner -- The Commissioner of the Bureau for Public Health or his or her designee.

3.4. Newborn Screening. -- The statutorily mandated screening of newborns by hospitals, birthing facilities, physicians or others.

3.5. Newborn Screening System. -- The coordinated effort by the bureau and West Virginia physicians who deliver and care for children, to ensure that each newborn child is screened for metabolic disorders before discharge from birthing facilities. Infants identified with a disorder must receive continuing care and treatment provided through a collaborative effort between the primary physician, medical specialist, the bureau, and community support services.

3.6. Office of Maternal, Child and Family Health. -- The office in the bureau that provides coordination and leadership in working with public and private community partners and families to assure the availability and use of health care for all mothers, infants and children including children with special health care needs.

3.7. Primary Care Provider. -- The physician, physician's assistant, nurse, nurse practitioner or other licensed medical professional responsible for the infant's health services during and/or after discharge from the birthing facility.

3.8. State Laboratory. -- The Department of Health and Human Resources, Bureau for Public Health's Office of Laboratory Services, that supplies newborn screening services to all birthing facilities in the state.

**§64-91-4. When Screening is Required.**

4.1. W. Va. Code §16-22-3 requires that all infants born in the state be screened for detection and control of diseases in newborn children as listed in section 5.

4.2. When the birth takes place in a licensed birthing facility the primary care provider must perform or cause to be performed newborn screening as listed in section 5 within 48 hours of birth, or before discharge from the birthing facility, whichever comes first.

4.3. If an infant is born in a non-hospital or non-birthing facility, including a home, the person in attendance at the birth must perform or cause to be performed the newborn screening as listed in section 5 within 48 hours of the birth.

4.4. If a specimen is unacceptable or a positive screen result occurs, the primary care provider must perform or cause to be performed a second screen.

**§64-91-5. Complete list of diseases and conditions.**

5.1. Every infant born in West Virginia must be screened for the diseases and conditions contained in this section.

5.2. Adrenoleukodystrophy

5.3. Argininosuccinic acidemia, ASA;

5.4. Beta-ketothiolase deficiency, BKT;

5.5. Biotinidase deficiency, BIOT;

- 5.6. Carnitine uptake defect, CUD;
- 5.7. Citrullinemia, CIT;
- 5.8. Congenital adrenal hyperplasia, CAH;
- 5.9. Cystic fibrosis, CF;
- 5.10 Galactosemia, GALT;
- 5.11. Glutaric acidemia type I, GAI;
- 5.12. Hearing deficiency, HEAR;
- 5.13. Hemoglobinopathies; including:
  - 5.13.a. Hemoglobin S/Beta-thalassemia, Hb S/Th;
  - 5.13.b. Sickle cell anemia, Hb SS;
  - 5.13.c. Sickle C disease, Hb S/C;
- 5.14. Homocystinuria, HCY;
- 5.15. 3-Hydroxy-3-methylglutaric aciduria, HMG;
- 5.16. Hypothyroidism, CH;
- 5.17. Isovaleric acidemia, IVA;
- 5.18. Long-chain hydroxyacyl-CoA dehydrogenase deficiency, LCHAD;
- 5.19. Maple syrup urine disease, MSUD;
- 5.20. Medium-chain acyl-CoA dehydrogenase deficiency, MCAD;
- 5.21. 3-Methylcrotonyl-CoA carboxylase deficiency, 3MCC;
- 5.22. Methylmalonic acidemia - Cbl A and Cbl B forms, Cbl A,B;
- 5.23. Methylmalonic acidemia-mutase deficiency form, MUT;
- 5.24. Multiple carboxylase deficiency, MCD;
- 5.25. Phenylketonuria, PKU;
- 5.26. Propionic acidemia, PROP;
- 5.27. Trifunctional protein deficiency, TFP;

- 5.28. Tyrosinemia type I, TYRI;
- 5.29. Very long-chain acyl-CoA dehydrogenase deficiency, VLCAD;
- 5.30. Lysosomal Storage Disorders;
- 5.31. X-Linked Adrenoleukodystrophy, X-ALD; and
- 5.32. Spinal Muscular Atrophy, SMA.

**§64-91-6. Screening Protocol.**

6.1. The primary care provider must perform, or cause to be performed, newborn screening listed in section 5 shortly after birth and before discharge from the birthing facility and send the specimen to the state laboratory to perform the tests.

6.2. The screening must be performed by trained personnel, according to the Clinical Laboratory Improvement Amendments (CLIA) standards as recommended by the American Academy of Pediatrics.

6.3. The Commissioner may update or modify the screening procedures according to screening protocol, technology, and current national standards.

6.4. If the primary care provider is unable to screen or cause to have screened the infant before discharge, then the primary care provider must refer the infant for an outpatient newborn screening.

6.5. For infants born in a non-hospital or non- birthing facility, including a home, the primary care provider must order an outpatient newborn screen.

6.6. A specimen must be collected on collection kits obtained through the state laboratory.

6.7. A specimen must be submitted to the state laboratory within 24 hours of collection through the U.S. mail or have the specimen ready for pick-up by courier service at a designated time and location.

**§64-91-7. Screening Fee Schedule.**

7.1. The bureau may bill the birthing facility or individual attending the birth for services provided for each newborn screen consistent with prevailing health insurance reimbursement rates for newborn screening to cover the administrative, laboratory, and follow-up costs associated with the performance of screening tests required by this rule.

7.2. No newborn may be denied testing required by this rule because of inability of the newborn's parents or legal guardian to pay the prescribed fee.

7.3. The bureau will periodically review the newborn screening program to determine the efficacy and cost-effectiveness of the program and determine whether adjustments to the program are necessary to protect the health and welfare of this state's newborns, and to maximize the number of newborn screenings that may be conducted with the funding available for the screenings.

7.4. The bureau shall prepare an annual report to be submitted to the legislature, and to be made available to any interested party, that will include actual expenses incurred and revenue generated by the newborn screening system each year.

**§64-91-8. Screening Reporting and Assistance to Afflicted Children.**

8.1. The birthing facility must record or cause to be recorded the newborn screening results in the infant's medical record.

8.2. Positive results on any screen specified in section 5, or any other diseases specified by the bureau, must be promptly reported to the bureau and the primary care provider by the director of the state laboratory performing the test.

8.3. The primary care provider must report all newborn screening results to the infant's parents or legal guardian.

8.4. Assistance with referrals must be offered by the bureau in cooperation with other state agencies to children determined to be afflicted with any disease specified in section 5 for medical and dietary needs.

8.5. When an infant is born in a non-hospital or non-birthing facility, including a home, the provisions of subsection 4.3. apply.

**§64-91-9. Confidentiality.**

9.1. Confidential information obtained while performing the required screenings may only be disclosed to:

9.1.a. Reporting sources;

9.1.b. Persons demonstrating a need essential to health-related research or care of the infant; or

9.1.c. As required by law.

9.2. Prior to receipt of confidential information, the requestor must agree to maintain the confidentiality and privacy of the information as required by law.